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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

United States Courts
Southern District of Texas
FILED
April 27, 2022

Nathan Ochsner, Clerk of Court

UNITED STATES OF AMERICA	§	
	§	Criminal No. <u>Under Seal</u>
v.	§	4:22-cr-211
	§	1,22 (1 211
AARON DEERE	§	

INDICTMENT

The Grand Jury charges that:

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

- 1. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et. seq. One of the primary purposes of the FDCA was to ensure that drugs for use in humans were safe and effective for their intended uses, and bore labeling containing only true and accurate information. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.
- 2. The FDCA defined a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles (other than food) intended to affect the structure or any function of the body of man, and articles intended for use as a component of any such articles. (21 U.S.C. § 321(g)(1)(C)). 21 U.S.C. § 321(g)(1)(B-D).
- 3. The FDCA defined a "new drug" as, with limited exceptions, any drug that was not generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended,

or suggested in its labeling. 21 U.S.C. § 321(p). Unless there was in effect with the FDA a new drug application ("NDA"), an abbreviated new drug application ("ANDA"), or an Investigational New Drug exemption ("IND)", a new drug was an unapproved new drug and cannot lawfully be entered into interstate commerce. 21 U.S.C. §§ 355(a) and 331(d).

- 4. Under the FDCA, "label" meant a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was defined more broadly as all labels and other printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article. 21 U.S.C. § 321(m).
- 5. "Prescription drugs" were drugs which, "because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug"; or a drug which was limited by an approved new drug application (under 21 U.S.C. § 355) for use under the professional supervision of a practitioner licensed by law to administer such a drug. 21 U.S.C. § 353(b)(1).
- 6. Prescription drugs were deemed to be misbranded if at any time prior to dispensing, the label of the drug failed to bear, at a minimum, the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A). The "Rx only" symbol was used on the label for prescription drugs, as opposed to over-the-counter drugs which did not contain that symbol on the label.
- 7. A prescription drug was also misbranded when it was not dispensed pursuant to a prescription of a practitioner licensed by law to administer such drug. 21 U.S.C. § 353(b)(1).
- 8. Under the FDCA, a drug was also misbranded if, among other things, the labeling of the drug did not bear adequate directions for use, 21 U.S.C. § 352 (f)(1)). "Adequate directions for use" meant directions under which a layperson could use a drug safely and for the purposes for which it was intended, 21 C.F.R. § 201.5. By definition, prescription drugs could not have adequate directions that allowed a layman to use them safely and for the purposes for which they were intended because

such drugs could only be used safely, if at all, at the direction, and under the supervision, of a licensed medical practitioner.

- 9. FDA-approved prescription drugs that complied with all of the relevant FDA regulations before they were dispensed were exempt from the adequate directions for use requirement. Those regulations included, among other things, requirements that: (a) the drug's label bear the statement "Rx only" prior to dispensing; and (b) a new drug's labeling be the same as the labeling approved by FDA. 21 C.F.R. § 201.100(b)(1) and (c)(2).
- 10. The FDCA prohibited the doing or causing to be done any act to a drug if the act was done while the drug was held for sale after shipment in interstate commerce and the act resulted in the drug being misbranded. 21 U.S.C. § 331(k).

DEFENDANT

- 11. Defendant **AARON DEERE** ("**DEERE**") created JJAM MARKETING AFFILIATES, LLC (EIN: 45-3969814) and SMARTDRUGSFORTHOUGHT.COM on or about December 5, 2011. **DEERE** was the owner of the online drug company and handled or supervised all operations for JJAM MARKETING AFFILICATES, LLC and SMARTDRUGSFORTHOUGHT.COM.
- 12. On or about December 5, 2011 to on or about March 19, 2021, **DEERE** manufactured and distributed Nootropic drugs via their website www.smartdrugsforthought.com.

CO-CONSPIRATORS

13. PERSONS A and B were employees at SMART DRUGS FOR THOUGHT who performed duties, as directed by **DEERE**, such as informational technology (IT), marketing, nootropic drug manufacturing, packaging, labeling, shipping, acquisition/transportation of bulk quantities of foreign sourced nootropic drugs, and customer complaints, for SMART DRUGS FOR THOUGHT.

- 14. PERSON A who agreed to open a Bank of America business checking account while falsely representing himself to be the President and primary owner of JJAM MARKETING AFFILIATES, LLC.
- 15. PERSON B was in operations and customer service and was the primary contact with online customers in handling shipping matters and inquiries about the products and orders.
- 16. PERSON C is affiliated with SHANGHAI SOYOUNG BIOTECH, INC. and DUJAN PHARM-TECH CO LTD. located in Shanghai, China. PERSON C trafficked bulk (SA Matthew Kessler kilogram) quantities of drugs into the United States and supplied businesses including SMART DRUGS FOR THOUGHT.

SMART DRUGS FOR THOUGHT

- 17. **SMARTDRUGSFORTHOUGHT.COM** ("the website") offered for sale a variety of products that were intended for use as drugs in that they were intended for use in the care, mitigation, treatment, or prevention of disease and/or to affect the structure or any function of the body. These drugs were prescription drugs because they were intended for the treatment of one or more diseases which were not amenable to self-diagnosis or treatment without the supervision of a medical practitioner.
- 18. The website claimed to be "Top Producers of Nootropics" and described "nootropics" as advanced nutraceuticals (nutrition derived compounds) that can improve mental functions such as cognition, memory, motivation, focus, mental processing, concentration, mood, and the biochemical factors involved in brain aging."
- 19. **DEERE**, SMARTDRUGSFORTHOUGHT.COM, and JJAM MARKETING AFFILIATES did not have an approved NDA, ANDA, or IND for any of their drug products.

NOOTROPIC DRUG PRODUCTS

- 20. Between August 10, 2018 and March 19, 2021, FDA-OCI Special Agent Matthew Kessler, acting in an undercover capacity, hereinafter referred to as the "UC," conducted three undercover purchases of nootropics from website www.smartdrugsforthought.com.
- 21. As a result of the UC purchases, the FDA-OCI Special Agent Matthew Kessler received twelve bottles of Neuro Wave Aniracetam, eleven bottles of Neuro Force Adrafinil, and seven bottles of Neuro Boost Piracetam.
- 22. On March 1, 2019, the UC ordered Adrafinil and Aniracetam capsules on smartdrugsforthought.com.
- 23. On March 10, 2019, FDA-OCI SA Kessler received and opened a parcel from SDFT at 12335 Kingsride Lane, 433, Houston, TX 77024 and observed the following: 8 sealed bottles of Neuro Wave Aniracetam, each bottle listed that each bottle contained 60 Vegetarian Capsules, 8 sealed bottles of Neuro Force Adrafinil, and 2 bottles of Neuro Boost Piracetam.
- 24. An FDA Forensic Chemistry Center (FCC) Case/Sample Summary Report dated May 31, 2019, revealed the portions of the Adrafinil, Aniracetam, and Piracetam capsules tested contained Adrafinil, Aniracetam, and Piracetam received by FDA-OCI SA Matthew Kessler on March 10, 2019 stemming from an UC on-line purchase form smartdrugsforthought.com.

25. <u>Neuro Force Adrafinil.</u>

- A) The Neuro Force Adrafinil page of the www.smartdrugsforthought.com website claimed that the product "increases wakefulness and concentration. Stimulates brain attentiveness and memory. The "What is Adrafinil" section of the website made the following statements:
 - i. "Dosage and Suggested Usage of Adrafinil" section. States "The ideal dosage of Adrafinil is between 600-1200mg...The drug can also be taken on a cyclic basis."

- ii. "Adrafinil was prescribed in France in 1986 as a treatment for narcolepsy due to its effects of wakefulness and alertness."
- iii. "Adrafinil is a stimulatory drug that is used by late shift workers . . . to help improve alertness and increase the feeling of wakefulness."
- B) The label on the Neuro Force Adrafinil bottle stated:
 - The products are distributed by: SMART DRUGS FOR THOUGHT, WWW.SMARTDRUGSFORTHOUGHT.COM, Houston, Texas.
 - ii. "A healthy way to stimulate your mind!"
 - iii. NEURO FORCE PRODUCT INFO: "Adrafinil is a mild stimulant that helps with sleepiness and inattention, that is commonly used to help combat fatigue.")
- C) The website did not require a prescription to purchase Adrafinil, and the product label failed to bear the "Rx Only" symbol.
- D) The website also stated "Adrafinil has never been approved by the FDA and is therefore, unscheduled and unregulated in the United States." In the (Kessler website under the "Shipping Information" header, under the "Attention:" section, "This compound has not been approved by the FDA and should be used for research purposes only".) "Buy Adrafinil section" of the website, there was a disclaimer stating that this compound has not been approved by the FDA and should be used for research use purposes only.

26. <u>Neuro Wave Aniracetam</u>

- A. The website listing for Neuro Wave Aniracetam stated, "Benefits cognitive functions including concentration, mental endurance, focus, memorization, and visual perception."

 The "What is Aniracetam" section of the website included the following statements:
 - i. "The short-term effects of Aniracetam include improvement in the mood. This is because the effective drug is efficient in influencing the chemicals, Seratonin and Dopamine ..."

- ii. "This nootropic has been reported to improve vigilance in patients with Alzheimer's, Parkinson's, cerebral infarction, anxiety depression, and the incidence of sleep disorders."
- iii. It is "also very effective in treating post-stroke depression and sleep disorders."
- B. The label on the Neuro Wave Aniracetam bottle stated:
 - The products are distributed by: SMART DRUGS FOR THOUGHT, WWW.SMARTDRUGSFORTHOUGHT.COM, Houston, Texas.
 - ii. "A HEALTHY WAY TO STIMULATE YOUR MIND!"
- iii. "SUGGESTED USAGE: The typical dosage for Aniracetam is from 750 mg 1500 mg three times a day."
- iv. "It increases memory as well as works efficiently for the overall enhancement of learning capacity in human beings."
- A. The website did not require a prescription to purchase Neuro Wave Aniracetams and the product label failed to bear the "Rx Only" symbol.
- B. Under smartdrugsforthought.com/product/buy-aniracetam/, under shipping information header, "This compound has not been approved by the FDA and should be used for research purposes only".

27. <u>Neuro Boost Piracetam</u>

- A. The label on the Neuro Boost Piracetam bottle stated:
 - The products are distributed by: SMART DRUGS FOR THOUGHT, WWW.SMARTDRUGSFORTHOUGHT.COM, Houston, Texas.
 - ii. "A HEALTHY WAY TO STIMULATE YOUR MIND!"
 - iii. "Piracetam is a nootropic drug that may be used to increase or improve cognitive and motor functions."
 - iv. The standard dosage of piracetam is 1600 mg thrice a day in the starting."

v. The website did not require a prescription to purchase Neuro Boost Piracetam and the product label failed to bear the "Rx Only" symbol.

COUNT ONE

Conspiracy to Unlawfully Distribute a Misbranded Drug (18 U.S.C. §371)

From about December 2011, and through in or around March 2021, the exact dates being unknown to the Grand Jury, in the Houston Division of the Southern District of Texas, and elsewhere,

Defendant

AARON DEERE

28. Knowingly and intentionally combined, conspired, confederated, and agreed together and with PERSON A, PERSON B, and PERSON C, to violate Title 21, United States Code, Sections 331(k) that is, to knowingly, intentionally, and unlawfully do or cause of any act to a drug while it was held for sale after shipment in interstate commerce which caused the drug to become misbranded.

PURPOSE OF THE CONSPIRACY

29. **DEERE** sought to enrich himself with the assistance of PERSON A, PERSON B, and PERSON C, by: (a) advertising, manufacturing, shipping, selling, and the doing or causing to be done any act to a drug while the drug was held for sale after shipment in interstate commerce and the act resulted in the drug being misbranded. Further, **DEERE**, PERSON A, PERSON B, and PERSON C, defrauded the public and the United States Food and Drug Administration by; (b) generating large profits from selling misbranded drugs (nootropics); and (c) diverting the proceeds from those misbranded drug sales for the personal use and benefit of **DEERE**.

MANNER AND MEANS OF THE CONSPIRACY

The manner and means by which **DEERE**, PERSON A, PERSON B, and PERSON C, sought to accomplish the purpose and object of the conspiracy included:

- 30. On or about December 29, 2011, **DEERE** opened a post office box under the entity, JJAM MARKETING AFFILIATES, LLC at a UPS Store located at 12335 Kingsride Lane, Houston, Texas. The post office box address was used to facilitate the receipt bulk quantities of nootropic drugs from foreign suppliers and to ship paid orders to customers.
- 31. PERSON A was employed by **DEERE** at Smart Drugs for Thought and per his employment duties, he picked up and returned shipments from customers and bottles used to package SMART DRUGS FOR THOUGHT manufactured nootropic drugs.
- 32. On or about December 5, 2011, **DEERE** and PERSON A opened a business bank account (x2494) at Bank of America in the name of JJAM MARKETING AFFILIATES, LLC. **DEERE** and PERSON A signed and presented to Bank of America, a corporate resolution where PERSON A fraudulently represented himself as the 95% owner and President of the business while **DEERE** fraudulently represented himself to be a 5% owner.
- 33. **DEERE** had full control and ownership of the account along with all the proceeds deposited. AARON DEERE solely managed all of the finances concerning JJAM MARKETING AFFILIATES, LLC.
- 34. PERSONS A and B were paid by **DEERE** in cash to work for the business.
- 35. On December 5, 2011, **DEERE** opened Bank of America account x2494 and he was the only person to use the account.

- 36. **DEERE** designed and established the SMART DRUGS FOR THOUGHT website and he wrote all the product descriptions on the website.
- 37. **DEERE** was selling nootropics on Amazon, the SMART DRUGS FOR THOUGHT nootropic labels were marked "for research use only" and "not for human consumption." **DEERE** had nootropics marketed for research purposes only, although he and PERSONS A, B and C were aware that the nootropics were marketed as a brain function enhancing supplements and that the products were consumed by buyers.
- 38. **DEERE** paid PERSON C \$1,147.00 via PayPal for the purchase and shipment of bulk nootropics chemicals on April 06, 2012. Another PayPal payment was made in the amount of \$1,363.00 to PERSON C for bulk nootropic chemicals on May 24, 2012. These payments were made to a PayPal account in the name of HE YONG.
- 39. **DEERE** made three additional PayPal payments for nootropics to PERSON C at an alternate account in the name of SUN FUSHENG (as translated).
- 40. Between August 31, 2016 and May 16, 2019, DEERE made six wire transfers to PERSON C at SOYOUNG INTL LIMITED totaling \$16,204.00 for the purchase and shipment of bulk nootropic chemicals from China.
- 41. **DEERE**, SMARTDRUGSFORTHOUGHT.COM and JJAM MARKETING AFFILIATES, LLC earned in excess of \$1,751,632.47 in proceeds received from the sales of nootropic drugs between February 2, 2012 and April 23, 2020 as follows:

	Sales or	Proceeds	
Entity	Payment Dates	Received	Source Documents
PayPal, Inc.	04/07/2013 to	\$1,184,618.17	PayPal Transaction History &
Acct. # 2288675471119959214	07/20/2017		BOA Acct 5860 2833 2494
Amazon, Inc.	04/12/2012 to	\$267,076.33	BOA Acct
jjammemory@gmail.com	09/10/2014		5860 2833 2494
Braintree – Wells Fargo	10/02/2015 to	\$278,945.53	Braintree Monthly Statements &
Merchant Services	10/13/2016		BOA Acct 5860 2833 2494
Account #9349 0001 2286			
Esquire Bank - Nuvei Merchant	05/07/2019 to	\$20,992.44	Esquire-Nuvei Monthly Statements
Account #9349 0001 2286	04/23/2020		& BOA Acct 5860 2833 2494

- 42. On or around December 8, 2011, **DEERE** opened a PayPal account in the name of PERSON A without his/her knowledge. **DEERE** registered the account for merchant sales on or around March 13, 2012.
- 43. PayPal sales between April 07, 2013 and July 20, 2017 totaled \$1,184,618.17, which was net of refunds, reversals, and denied payments. Over 18,384 nootropic drug products were sold in U.S. Dollars alone.
- 44. Between April 09, 2013 and December 18, 2017, **DEERE** made 311 transfers from the PayPal account to the Bank of America JJAM Marketing Affiliates, LLC bank account which totaled \$1,022,040.31.
- 45. **DEERE** opened an Amazon account using email address jjammemory@gmail.com on March 7, 2012. The account was registered for merchant activities on March 12, 2012.
- 46. **DEERE** had 58 disbursements to the JJAM MARKETING AFFILIATES, LLC Bank of America account x2494 totaling \$267,076.33, which are net of applicable fees. **DEERE** had full and exclusive control of these proceeds and used them to pay for business and personal expenses.
- 47. On or about September 29, 2015, **DEERE** opened the SMART DRUGS FOR THOUGHT Braintree (Wells Fargo Merchant Services) merchant sales account using PERSON A's name and date of birth.
- 48. **DEERE** described his business sales to include non-clinical scientific research materials and that students and researchers are the primary customers.

- 49. Braintree statements showed gross sales of \$296,888.75 with net disbursements, after fees and chargebacks, totaling \$280,488.08. Bank of America statements for JJAM Marketing Affiliates account x2494 shows 257 deposits of proceeds from Braintree totaling \$278,945.53 between October 02, 2015 and October 13, 2016.
- 50. On or about February 11, 2019, **DEERE** submitted an account application to open a merchant sales account with Esquire Bank and Nuvei Payment Technology Network. **DEERE** printed PERSON A's name and forged his/her signature on the application.
- 51. In Nuvei's Abbreviated Summary, it is established that JJAM sells "natural nootropic supplements."
- 52. Esquire Bank–Nuvei merchant account statements between March 2019 and April 2020 show 366 sales. Gross sales totaled \$21,156.73 between May 07, 2019 and April 23, 2020. There was \$140.11 in chargebacks, which reduces the total to net disbursements of \$20,992.44, which matches the total Esquire-Nuvei deposits into the JJAM MARKETING AFFILIATES, LLC Bank of America account x2494.

COUNT TWO Misbranding of a Drug 21 U.S.C. §§331(k), and 333(a)(2)

The United States Attorney alleges and incorporates by reference herein the allegations contained in Paragraphs [1 - 52] of this Indictment.

- 53. From approximately December 5, 2012 to March 19, 2021, in the Southern District/Texas, the defendant, **AARON DEERE** and other unindicted co-conspirators, did with the intent to defraud and mislead, did and caused an act with respect to a prescription drug namely, Adrafinil while such drug was held for sale and after shipment in interstate commerce, which resulted in such drugs being misbranded in one or more of the following ways:
 - a. The labeling failed to bear directions for use, within the meaning of 21 U.S.C. §352(f)(1).

- b. The label failed to bear the symbol "Rx only" prior to dispensing, within the meaning of 21 U.S.C. § 353(b)(4)(A)
- c. The drug was dispensed without a prescription of practitioner licensed by law to administer the drug. 21 U.S.C. § 353(b)(1).

NOTICE OF CRIMINAL FORFEITURE 28 U.S.C. § 2461(c); 18 U.S.C. § 981(a)(1)(C)

Pursuant to Title 28, United States Code, Section 2461(c) and Title 18, United States Code, Section 981(a)(1)(C), the United States gives notice to the Defendant, **AARON DEERE**, that in the event of conviction of the offenses charged in Counts 1-2 of this Indictment, the United States intends to seek forfeiture of all property, real or personal, which constitutes or is derived from proceeds traceable to such offenses.

Money Judgment

Defendant is notified that upon conviction, a money judgment may be imposed equal to the total value of the property subject to forfeiture in the approximate value of \$1,751,632.47.

Substitute Assets

Defendant is notified that in the event that property subject to forfeiture, as a result of any act or omission of Defendant,

- (A) Cannot be located upon the exercise of due diligence;
- (B) Has been transferred or sold to, or deposited with, a third party;
- (C) Has been place beyond the jurisdiction of the court;
- (D) Has been substantially diminished in value; or

(E) Has been commingled with other property that cannot be divided without difficulty,

it is the intent of the United States to seek forfeiture of any other property of the Defendant up to the total value of such property pursuant to Title 21, United States Code, Section 853(p), incorporated by reference in Title 28, United States Code, Section 2461(c).

A TRUE BILL

Signature on File

FOREPERSON OF THE GRAND JURY

JENNIFER LOWERY ACTING UNITED STATES ATTORNEY

By: Tina Ansari

Tina Ansari Assistant United States Attorney